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K052169

10.0 SUMMARY OF THE SAFETY AND EFFECTIVENESS

International Medsurg Connection Surgical Drape

Manufacturer:	International Medsurg Connection, Inc. 935 N Plum Grove Road, Suite F Schaumburg, Illinois 60173-4770
Regulatory Contact:	Manny Gupta Vice President / General Manager International Medsurg Connection, Inc. 935 N Plum Grove Road, Suite F Schaumburg, Illinois 60173-4770
Telephone:	847-619-9929
Date Summary Prepared	August 5, 2005
Product Trade Name:	IMC Surgical Drapes - Multiple
Common Name:	Surgical Drape.
Classification:	Class II
Predicate:	IMC Drapes, Reference K050538 owned by International Medsurg Connection.
Description:	Surgical Drapes including various sizes and configurations of table covers, flat drape sheets, Lap drapes, cardiovascular drapes, head & neck drapes, general use drapes, cysto drapes, c-section drapes, orthopedic drapes and specialty drapes.

Intended Use:
International Medsurg Connection's Surgical Drape is intended to be used as Patient protective coverings used to isolate incision sites and protect against contamination during surgical procedures.

Substantial Equivalence:
The International Medsurg Connection Surgical Drapes are substantially equivalent to IMC Drapes sold by International Medsurg Connection, Reference K050538.

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They provide the following characteristics:

Intended use is the same
Similar configurations
Similar materials

Summary of testing:

All material used in the fabrication of the IMC Surgical Drapes were evaluated for:

Test	Standard
Cytotoxicity	ISO 10993 – Part 5
Skin Irritation	ISO 10993 – Part 10
Skin Sensitivity	ISO 10993 – Part 11
Systemic Toxicity	ISO 10993 – Part 11
Flammability	16 CFR Part 1610
Hydrostatic Pressure	AATCC 127
Impact Penetration	AATCC 42
Lint	IST 160.1
Tensile Strength	ASTM D5034

ATTACHMENT E
DRAPES LIST

Catalog Number	Description
Table Covers	
270-2500	Mayo Stand Cover
270-2510	Mayo Stand Cover, X-Large
270-2309	Table Cover, Reinforced
270-2311	Table Cover, Reinforced
270-2316	Table Cover, Reinforced
270-2313	Table Cover, Heavy Duty with Extension
Flat Drape Sheets	
270-2410	Half Drape
270-2412	Medium Drape
270-2416	Three Quarter Drape, Reinforced
270-2417	Large Drape
270-2419	Full Drape
Lap Drapes	
270-3003	Laparotomy Drape
270-3008	Laparotomy Drape (with pouches)
270-3005	Trans Laparatomy Drape
270-3009	Ped Laparatomy Drape
270-3103	Major Abdominal Laparoscopic Drape
270-9101	Laparoscopy Drape
270-9103	LAVH Drape
270-3751S	Laparoscopic Perineal Drape
Cardiovascular Drapes	
270-4001	Cardio / CV Drape
270-4006	CV Split Drape
270-4007	Bilateral Split Drape
Head & Neck Drapes	
270-7001	EENT Split Drape
270-7002	Thyroid Drape
270-7003	Thyroid T-Drape
270-7008	Head Bar Drape
270-7009	Head Turban Drape
General Use Drapes	
270-2460	Legging
270-2461	Legging
270-2405	Utility Drape
270-2408	Utility Drape Extra Large
270-4002	Top Drape
27—4206S	Bottom Drape
27-4207S	Side Drape
270-2498	Split Drape
270-2600S	Abdominal Drape
Cysto Drapes	
270-5090S	Cysto T-Drape
270-5091S	Cysto Drape
270-9001	Lithotomy Drape
270-9103	Lithotomy Drape

ATTACHMENT E
DRAPES LIST

C-Section Drapes	
270-6101	C-Section Drape
270-6102	C-Section Drape
Orthopedic Drapes	
270-8101	Arthroscopy Drape
270-8102	Arthroscopy Drape
270-8002	Extremity Drape
270-8003	Extremity Drape
270-8005	Hand Drape
270-8301	Ortho Split Drape
270-8004	Bilaterial Limb Drape
270-8201	Hip Drape
270-8401S	Shoulder Drape with pouch
270-2499	U-Drape
Specialty Drapes	
270-8412	Beach Drape
270-2540S	Chest/Breast Drape
270-6003	Circumcision Drape

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

NOV 17 2005

Mr. Manny Gupta
Vice President/General Manager
International Medsurg Connection, Incorporated
935 North Plum Glove Road, Suite F
Schaumburg, Illinois 60173-4770

Re: K052169
Trade/Device Name: IMC Surgical Drapes-Various Types, Sizes and Configurations, Per Attached List
Regulation Number: 878.4370
Regulation Name: Surgical Drape and Drape Accessories
Regulatory Class: II
Product Code: KKX
Dated: November 8, 2005
Received: November 9, 2005

Dear Mr. Gupta:

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration.

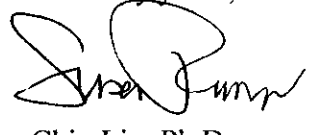
If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to such additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish further announcements concerning your device in the Federal Register.

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Part 801); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.

This letter will allow you to begin marketing your device as described in your Section 510(k) premarket notification. The FDA finding of substantial equivalence of your device to a legally marketed predicate device results in a classification for your device and thus, permits your device to proceed to the market.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please contact the Office of Compliance at (240) 276-0115. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR Part 807.97). You may obtain other general information on your responsibilities under the Act from the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638-2041 or (301) 443-6597 or at its Internet address http://www.fda.gov/cdrh/industry/support/index.html.

Sincerely yours,



Chiu Lin, Ph.D.
Director
Division of Anesthesiology, General Hospital,
Infection Control and Dental Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

Indications for Use

510K Number : K052169

Device name: IMC Surgical Drapes – Various types, sizes and configurations, per attached List.

Indication For Use:

This device is intended to be used as protective coverings used to isolate incision sites and protect against contamination during surgical procedures.

This submission includes drapes that will be sold both sterile and non-sterile. Non-sterile drapes are to be sold to OEMs for EtO sterilization according to ISO 11135. Sterile drapes are to be sold directly to users after EtO sterilization validation to ISO 11135.

Prescription Use X AND/OR Over-The counter Use
(Partb21 CFR 801 Subpart D) (21 CFR 801 Subpart C)

(PLEASE DO NOT WRITE BELOW THIS LINE-CONTINUE ON ANOTHER PAGE IF NEEDED)

Concurrence of CDRH, Office of Device Evaluation (ODE)

Sheila A. Murphy MD 11/16/05
(Division Sign-off)
Division of anesthesiology, General Hospital.
Infection Control Dental Devices